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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,738	08/12/2002	Richard D. Fuerle	RF01-CIP	6596
27797	7590	06/16/2004	EXAMINER	
RICHARD D. FUERLE 1711 W. RIVER RD. GRAND ISLAND, NY 14072			KETTER, JAMES S	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/064,738

Applicant(s)

FUERLE, RICHARD D.

Examiner

James S. Ketter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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The disclosure is objected to because of the following informalities: At page 1, in the continuing data, the patent number of the parent file has been omitted.

Appropriate correction is required.

Claims 1-20 are objected to because of the following informalities:

While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim," "The invention claimed is" (or the equivalent). See MPEP § 608.01(m).

Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 9 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Coffey et al. (U, newly cited).

The instant claims are drawn to modified microbes made by a recited process, such that the microbes, more narrowly recited as viruses, have a greater affinity for target cells, more narrowly recited as human cells or cancer cells.

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Coffey et al. teaches, e.g., at the abstract, reovirus which act to regress tumors in mice when injected into said tumors. At Figure 3, it is taught that the reovirus replicated in the tumor mass but not in the surrounding normal tissues. Since reovirus normally infects humans, the reovirus of Coffey et al. would inherently target human cells.

The instant claims are presented as product-by-process claims, and as such, are examined as the product.

The term “modified” is not clearly defined. See the rejection under 35 USC § 112, second paragraph, below. As such, any microbe might be viewed as “modified” in that it varies from some other strain of the same species or virus.

Claims 1-6, 8, 9 and 11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Gnant et al. (V, newly cited).

Instant claims 1-6, 8, 9 and 11-14 are drawn to modified microbes made by a recited process, such that the microbes, more narrowly recited as viruses, have a greater affinity for target cells, more narrowly recited as human cells or cancer cells. Claims 15-19 are drawn to a modified virus which attacks cancer cells but not normal cells, produced by the recited process.

Gnant et al. teaches, e.g., at the abstract, vaccinia virus which act to regress tumors in mice when injected systemically. The rate of expression of a transgene was 1000- to 10,000-fold higher in tumors than normal tissue, indicating that cancer cells are attacked selectively over normal cells. Since vaccinia virus normally infects humans, the vaccinia virus of Gnant et al. would inherently target human cells, including human tumor cells in general.

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The instant claims are presented as product-by-process claims, and as such, are examined as the product.

The term “modified” is not clearly defined. See the rejection under 35 USC § 112, second paragraph, below. As such, any microbe might be viewed as “modified” in that it varies from some other strain of the same species or virus.

Claims 1-6 and 8-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Heise et al. (W, newly cited).

Instant claims 1-6 and 8-20 are drawn to modified microbes made by a recited process, such that the microbes, more narrowly recited as viruses, have a greater affinity for target cells, more narrowly recited as human cells or cancer cells. Claims 15-19 are drawn to a modified virus which attacks cancer cells but not normal cells, produced by the recited process. Claims 10 and 20 recite that the viruses may be adenoviruses.

Heise et al. teaches, e.g., at page 849, left-hand column, at the full paragraph, adenovirus dl-1520 which acts to regress tumors in human trials (page 850, left-hand column, at the first and second full paragraphs, and the paragraph bridging the columns.) The safety of the virus in these trials indicates selective replication in and therefore destruction of cancerous tissue. Since adenovirus normally infects humans, the adenovirus of Gnant et al. would inherently target human cells, including human tumor cells in general.

The instant claims are presented as product-by-process claims, and as such, are examined as the product.

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The term “modified” is not clearly defined. See the rejection under 35 USC § 112, second paragraph, below. As such, any microbe might be viewed as “modified” in that it varies from some other strain of the same species or virus.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a very broad genus of microbes, e.g., claim 1 encompassing essentially any strain or species of microorganism which would be infective. No disclosure of particular mutations harbored by any of the claimed microbes is present in the specification. For a particular microbe to be specifically targeted to a particular tumor type, and furthermore to be less specific for non-tumor cells, it must possess a structure, i.e., genetic make-up, to cause that specificity. However, given the vast number of disease states in the vast number of cell types in existence, it is apparent that many different structures would be encompassed. Neither the specification nor the art teaches a structure-function relationship between microbes and potential

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target cells such that the structures of the microbes, i.e., genetic make-up, could have been envisioned for the entire scope of the claims at the time of filing. As such, Applicant would not have conveyed to one of skill in the art that he was in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of the instant claims is drawn to a “modified” microbe or virus. However, the term “modified” is not clearly defined. In the absence of a clear definition, any microbe might be viewed as “modified” in that it varies from some other strain of the same species or virus. Thus, it is not apparent what limitation this term actually places on the instant claims, leaving the metes and bounds unclear.

Certain papers related to this application, OTHER THAN OFFICIAL RESPONSES, may be submitted directly to the Examiner by facsimile transmission at (571) 273-0770. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). (703) 872-9306 may be used without notification of the Examiner, with such faxed papers being handled in

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the manner of mailed responses. Applicant is encouraged to use the latter fax number unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Jsk
June 10, 2004



JAMES KETTER
PRIMARY EXAMINER